# Public Comment
# Jeannette Burmeister

*Ampligen: East Germany All Over Again*

My name is Jeannette Burmeister. Before getting sick with ME 6-½ years ago, I was practicing international law as an attorney admitted in California and Germany in the San Francisco and Palo Alto office of the biggest law firm in the world, Baker & McKenzie LLP.

I am about to become a citizen of the United States. I was born and raised in communist East Germany where travel was possible only to the countries of the Eastern Bloc. Even some of those countries were off limits for East Germans. When the wall came down, I was 18 years old. Up until then, I couldn't visit, or be in touch with, my relatives in West Germany: my uncle, my cousins, my second cousins, my cousins once removed, my great aunts and uncles. I didn't expect to ever be able to. Some people tried to climb over the wall, make their way through Check Point Charlie in a secret, custom-made compartment of a car, swim across border rivers, sneak across the Baltic Sea via a small inflatable boat or on an air mattress during a foggy night or fly across the border in a hot air balloon. Few actually made it. Many were shot by border guards or automatic machine guns, killed by mines or drowned during their attempts. Others were incarcerated for trying to escape or merely planning to try. I was enough of a realist to be resigned to the fact that East Germany was going to be it for me, for the rest of my life.

Then, the wall came down in 1989. Suddenly, I was free to live where I chose and to visit, or live with, any of my family members. Moving to the US more than 13 years ago was a dream come true despite my limited English skills because, for more than half of my life at that point, I thought I could never even be a tourist here, let alone a resident, and now soon a citizen. I will be a proud American. I feel immensely grateful for the opportunities I've been given in this country.

Sadly, a lot of these opportunities vanished when I got sick with ME. I am currently 100% disabled and unable to work. For the most part, I am also unable to travel, socialize, exercise, read for prolonged periods of time, do my fair share of housework and, most sadly, I have not been able to play with, or take care of, my 2-year old daughter Aimee in more than half hour or so increments. My husband, Ed, and I endured three grueling IVFs and beat 2% odds to have her. After all that, I get to see Aimee in person only for long weekends about every 3 weeks because Aimee and Ed live in the San Francisco Bay Area and I live in Incline Village, NV. The Bay Area has been my home for the last 13 years, but Ed and I saw no other option for a chance of recovering some of my health than for me to move to Incline Village earlier this year to start treatment with the immune-modulating drug Ampligen.

But first, let me tell you a bit about Aimee. She is the perfect blend of Ed and me, which is a relief after conceiving in a lab. She has my eyes and my hair. Her nose is a combination of Ed's and my nose. Her mouth seems to be still deciding whom it takes after. Aimee has Ed's long legs and my strong will. She jabbers all the time. That one is mostly Ed. She loves shoes. I've got to believe that that one is me. Aimee loves her gymnastics classes, which are basically a safe place to climb and jump. She enjoys kicking and throwing the ball and pushing around her "Püppchen"

(little doll) in her baby stroller. But her favorite thing to do is probably meeting up with her many friends at the park. She is more comfortable with boys than girls. She got this neither from Ed nor from me. She has a hard time eating solid food for some reason. She definitely didn't get that from her parents. She has allergies to something. To what we are not totally sure of, but it doesn't seem to slow her down too much. She loves books and has not caught on yet to the fact that the man with the yellow hat seems a little creepy; she focuses mostly on George. She can say things like, "Beethoven" (don't ask!) or “dinosaur" but she can't pronounce our nanny's name, Monika. So, for now, Monika is "market" and luckily, Monika is not offended. Aimee is and will be my only child and I am missing out on pretty much all of this.

So, why would I (and Ed) make such a tremendous sacrifice for a drug? Ampligen is administered via infusion twice a week. It is available in only 5 places in the country. Besides Incline Village, those places are New York City, Salt Lake City, Miami and North Carolina. The drive from the Bay Area to Lake Tahoe is about 4 hours without traffic and bad weather. Based on doctor’s orders, commuting twice a week is not an option because that would be much too strenuous for me and defeat the purpose of the treatment, retrieving some of my functioning. Because of my physical limitations, I have to rely on my husband and friends to drive me home to the Bay Area and back to Incline Village about every 3 weeks.

The reason for the limited availability of Ampligen is that it is an experimental drug, i.e., it has not been approved by the FDA. As an experimental drug, it is available for physicians to administer to their patients only as part of an open-label (i.e., not placebo-controlled) trial after a very labor and time-intensive approval process. Most of the few ME specialists don’t have the time and resources to invest in becoming an Ampligen site. Furthermore, without FDA approval, health insurance companies usually don’t pay for the drug. Because of the limited availability and the drug’s high price, very few patients are in a position to receive it. Most don’t have the financial means to pay for the drug and infusion costs alone: depending on the dose, between about $15,000 and $30,000 per year. Who can afford that plus the costs for moving to an Ampligen location plus having their partner give up their job to move with them or, alternatively, pay for the costs of a second home at an Ampligen site? And even if one can afford a second home, but not the loss of the income from their partner’s job, how many people can tolerate leaving their immediate family behind? The answer is loud and clear: There are less than 50 patients currently on Ampligen.

This is despite the fact that Ampligen has been proven to be extremely effective in a sub-group of ME patients, a patient population that has no other approved treatment because the government spends more money on hay fever than on this debilitating neuro-immune disease that affects an estimated minimum of 1 million patients in this country alone, plus their families. Ampligen has very few side effects and is amazingly safe. I had some negative reactions in the beginning, but I have been side-effect-free for a few months now after my doctor adjusted the dose and rate of infusion. Everybody who truly understands the debilitating nature of this disease would agree that the risk-benefit analysis of the drug clearly favors the approval of Ampligen in accordance with the FDA rules and regulations. Since Ampligen first was used in ME patients in 1988, many drugs with much more serious side effects than Ampligen have been approved for conditions less serious than ME. This drug has improved my quality of life quite dramatically. It is the only treatment that has done so. I am far from well, but since I only recently started res-

ponding, I expect my symptoms to improve further while I continue receiving the drug, as many other Ampligen patients' symptoms have over time. This is why Ed and I are making the sacrifices we are making. Ampligen is my best, and currently my only, chance at regaining some of my health and it is not available any closer to home than Incline Village.

So, why is Ampligen not FDA approved 24 years later? Because the CDC and NIH have, over nearly three decades, taken the unfounded and preposterous position that ME is a non-serious, psychological illness, which exists merely in patients' heads and which only requires exercise and psychotherapy to be cured. Hillary Johnson has documented the repugnant mocking and ridiculing by those two agencies meticulously in her book, "Osler's Web." From Gary Holmes of the CDC creating his own Statue of Liberty cartoon reading, "Give me your tired, your weak, your EBV-positive, yearning to be diagnosed" to Jon Kaplan, also with the CDC, opining, "They call us, they write us. They write their congressmen. They've got more energy than *I* do…." Another CDC employee was worried at the time that demeaning patients in this way would come back to haunt the agency. Funny thing: It never did.

Over the years, CDC and NIH have learned to clean up their act with respect to being more politically correct about ME and paying lip service in accordance with their prescribed task: to investigate threats to the health of the community. But their inactions speak louder than their words. There is no substance, just empty words. So it comes as no surprise that the FDA, a government agency, has not approved a drug for a crippling condition that two other agencies consider to be joke.

During the recent FDA Stakeholder meeting, the FDA, for the first time, as far as I am aware, labeled ME as "serious and life-threatening" condition. The FDA representatives on that call seemed sincere in their willingness to finally take our disease seriously. However, there was no detectable awareness of the serious lack of the FDA's credibility due to the deplorable history of the agency with this disease, no appropriate sense of urgency and no obvious attempt to make up for lost time. After nearly three decades of stalling, patients were shockingly told that, "We [the FDA] are just getting started." We were told that, as far as the FDA is concerned, there are currently no established biomarkers for ME and therefore, no ways to evaluate the efficacy of a drug. In other words, it's not the FDA's fault that, after all this time, there is no approved drug treatment for ME. And just like that, the ball is back in the disabled patients' court.

To say that there are no biomarkers for ME is simply not true. We have NK cell function, cytokine levels, high viral titers, VO2 max and many more abnormalities that ME patients show consistently. Especially the 2-day VO2 max test and the NK cell function test, if repeated periodically, are very reliable tests for ME. To be told by the FDA, after all these years, that its approval must wait for further biomarker studies—which most likely will not be forthcoming any time soon because of the lack of funding for the disease nobody wants to touch, certainly not the NIH and the CDC—is a circular argument and it is beyond disheartening.

One can't help but wonder if this is not the perfect set-up for denying the approval of Ampligen yet again, a decision regarding which by the FDA is due by February of next year. One also can't help but wonder whether government egos and the fear of embarrassment over admitting the decades-long neglect and abuse of a large and very sick patient group that has been thrown to

the wolves isn't a powerful motivator to keep the status quo. No approved drug—ergo, no serious illness—ergo, nobody is at fault for the shameful history with a debilitating disease. And finally, health and disability insurance companies stand to lose billions if ME were given the attention and classification by the government it deserves. One has to wonder how strong the insurance lobby is. Never mind that giving in to egos and lobbyists on this issue is tantamount to selling out millions of ME sufferers and their families. Keeping children from having their parents raise them and keeping parents from seeing their children grow up is just one manifestation of this contemptible approach.

Living with ME has been described as dying a slow and agonizing death. Some people don't have the strength to hang on any longer because of the relentless nature of the many and severe symptoms, which make getting through the day feel like a marathon for patients who can hardly walk a block. Add to that the ridicule, abuse, blame and degradation. How does one go on without any hope for a treatment during one's lifetime? Nobody is keeping track of the number of suicides in this disease. How convenient! But we do know that it's high because we all have lost friends to suicide. Not only is the government not providing anywhere near adequate amounts of research money for ME (MS research, e.g., gets funded about 30 times more than ME research despite the fact that there are a lot less MS than ME patients and they are often more functional than ME patients), it is also not approving the one drug that we know works for patients with a certain biomarker profile, Ampligen. Don't kid yourself, FDA! Making the unsupportable decision—again—not to approve Ampligen would be equivalent to letting people die: quite directly by withholding an effective drug and indirectly by quashing the hope we so desperately need!

Aimee and I video-chat every night and sometimes, she gets silly and chants, "Mami, Mami, Mami, Mami, Mami …" Like she is rooting for me. Sometimes, she gets sad and says "Mami, come home!" The other night, when Ed arrived at home from work, Aimee was asking about me. She thought I was still in the car about to come into the house. When Ed explained to Aimee that "Mami is away for a doctor's appointment," she cried. When he told me about this, I cried.

Out of the last 117 days, I have held Aimee on 27 days. I will not be able to go home to see her in her Halloween costume because Halloween is on a Wednesday this year and I have to be in Incline Village for my infusion early on Thursday morning.

So, when will I be a meaningful part of my daughter's life again? That depends solely on the FDA finally doing the right thing—medically, scientifically and morally—by approving Ampligen. It's a long overdue decision, but I am not holding my breath. I don't say this lightly, but this very much feels like East Germany all over again. This time, I am not separated from my family by a wall, but by government agencies, which, for the last decades, have consistently shown themselves to be irresponsible, arrogant and insensitive to human lives and suffering. The FDA must begin the process of turning this situation around by approving Ampligen! According to the FDA, there are currently only 10 new drug applications for ME, most of which are for supplements. ME is a crippling disease, which has destroyed many lives. We need something more potent than a supplement and we need it now! We have no approved drug treatment. None! And yet, Ampligen has been proven, for 24 years, to be a safe and effective drug for ME patients. With the current drug application for Ampligen, the FDA has a unique opportunity to demonstrate that it is starting to take ME seriously. We will all find out by February of 2013.